IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA ex rel. ROBERT A. FRY,	)	
Plaintiffs,	)	
v.	)	**Civil Action: 3:03-0842** **Hon. Aleta Trauger** **Magistrate Judge Knowles**
GUIDANT CORPORATION, its predecessor Cardiac Pacemakers, Inc., a division of Eli Lilly and Company,	)	
Defendant.	)	

DEFENDANT GUIDANT CORPORATION'S RESPONSE
TO RELATOR'S MOTION TO COMPEL AND FOR SANCTIONS

I. INTRODUCTION

While Guidant vigorously opposes Relator's Motion to Compel and for Sanctions, it welcomes the Court's review of the conduct of discovery to date. Guidant anticipates that, once the overheated claims of Relator's Motion give way to the facts, the Court will deny the Motion and assist the parties in structuring a rational discovery protocol in this unusual case.

II. BACKGROUND

Guidant[1] manufactures pacemakers and other implantable cardiac devices (ICDs). Guidant sells its ICDs to hospitals for use in treating patients with serious heart conditions. For hospital patients eligible for Medicare or Medicaid, the costs of Guidant's ICDs as well as the costs of the surgical procedures to implant them, can be submitted to the United States for reimbursement. (Ans. to Sec. Am. Compl. ¶¶ 7-8).

[1] The medical devices at issue in this case were designed and manufactured by Cardiac Pacemakers, Inc., a wholly owned subsidiary of Guidant Corporation. The devices were sold by Guidant Sales Corporation, a wholly owned subsidiary of Cardiac Pacemakers, Inc. (Ans. to Sec. Am. Compl. fn. 1).

On September 11, 2003, Relator, Robert A. Fry ("Relator"), filed this *qui tam* action against Guidant alleging violations of the federal False Claims Act ("FCA"). (Docket No. 1). Relator alleged that Guidant had engaged in a fraudulent scheme to conceal the availability of warranty and Cardiassure credits from hospitals for more than two decades. (*See generally* Compl.). The Complaint was filed under seal, but a copy was served on the United States. (Compl. ¶ 24).

Relator filed an Amended Complaint in 2004, which was followed by a Second Amended Complaint on May 4, 2006. (Docket No. 94). After initially declining to intervene, the United States moved to intervene on October 11, 2006 (Docket No. 132), which motion was granted on November 2, 2006 (Docket No. 137). After intervening and "taking over" the case under the FCA, however, the United States did little thereafter. The government has still not filed a Complaint-in-Intervention.

Continuing the unusual chain of events which has characterized this case, Relator – and not the United States as intervening party and the real party-in-interest – propounded broad discovery requests on February 2, 2007. (*See* Relator's First Set of Interrogatories to Defendant Guidant Corporation, attached as Exhibit 1, and Relator's First Request for Production of Documents to Defendant Guidant Corporation, attached as Exhibit 2). To date, the United States has not propounded any discovery to Guidant, nor has it made any substantive response to the discovery Guidant propounded to it.

At about the same time that Relator was serving its discovery requests in the United States' case, Guidant elected to change the national law firm assisting the Waller, Landsden firm, and retained Shook, Hardy & Bacon, L.L.P. to be the new national counsel. Contrary to Relator's assertions, prior to the deadline for its responses, Guidant's Nashville

counsel contacted Relator's counsel to arrange a meeting to introduce the new lawyers involved in the case and to discuss Guidant's discovery responses. Due to the unavailability of Relator's counsel, this meeting could not be scheduled until March 8, 2007 – one day after Guidant's responses were due.[2] During the meeting, Guidant's counsel requested its first – and only – extension to respond to Relator's discovery requests. Relator's counsel agreed to grant a 20-day extension. Neither the United States nor Relator's counsel suggested in any way that Guidant's request for an extension was untimely or that Guidant had "waived" its ability to object to Relator's discovery requests by accommodating Relator's schedule for the meeting at which the extension request was made. Nevertheless, on March 15, nearly a week later, Relator's counsel sent a letter purportedly "confirming" a very different sort of agreement; in this letter, Relator's counsel announced that, because the request for an extension came thirty-four days after the discovery requests were served, Guidant had waived its objections. (Letter from R. Fisher to J. Weaver, dated March 15, 2007, attached as Exhibit 3).

Guidant served its responses to Relator's discovery requests on April 2, 2007, consistent with the extension granted. In those responses, Guidant agreed to produce certain of the information requested, and interposed objections in conformity with the Federal Rules of Civil Procedure. (*See* Defendant Guidant Corporation's Responses to Relator's First Set of Interrogatories, attached as Exhibit 4, and Defendant Guidant Corporation's Responses to Relator's First Set of Requests for Production of Documents to Defendant Guidant Corporation, attached as Exhibit 5). On April 13, 2007, Relator's counsel sent a letter complaining angrily about Guidant's discovery responses. (Letter from R. Fisher to J. Weaver, dated April 13, 2007,

[2] Relator states that Guidant's response was due on March 5, 2007. Guidant, however, believes that its discovery responses were due on March 7, 2007, thirty-three days after they were served pursuant to Federal Rules of Civil Procedure 6(e) and 34(b).

attached as Exhibit 6). Rather than responding in kind, Guidant wrote the next business day suggesting that the parties make an effort to meet to "try to resolve what [Relator] believe[s] are the deficiencies in Guidant's discovery responses through direct discussions." (Letter from J. Weaver to R. Fisher, dated April 16, 2007, attached as Exhibit 7). It was specifically anticipated that this meeting would also permit Guidant to discuss the United States' failure to properly respond to Guidant's discovery directed to the government. The parties met on May 8.

At the May 8 meeting the case turned stranger still. Guidant was advised that the United States could not provide a single document demonstrating a false claim – the most basic predicate for prosecution of a FCA case – despite being involved in the case for more than three years and six months after having sought to intervene for "good cause." Even though Guidant was the only party at the meeting that did not bear any burden of proof in the case, it proposed a mechanism to move the case forward and test the Relator's allegations. Guidant proposed a logical, phased discovery protocol in which it would begin a rolling production of documents notwithstanding the government and Relator claiming to be unable to provide any actual false claim. Specifically, Guidant proposed to produce documents concerning replacement ICD procedures performed at the three hospitals identified in the Second Amended Complaint for the three years preceding the filing of the original Complaint. After such production, the parties could reassess what – if any – additional discovery would be necessary. Guidant understood Relator's counsel to have rejected this offer.

Guidant, however, continued the dialogue by providing a detailed response to Relator's complaints about Guidant's discovery responses. (Letter from M. Desai to R. Fisher, dated May 25, 2007, attached as Exhibit 8). In that letter, Guidant informed Relator that it was in the process of gathering responsive documents and a rolling production was underway based

on the proposal made by Guidant at the May 8 meeting – the only proposal made by any party to actually begin discovery. Guidant provided Relator with, and requested from Relator, additional clarification on several requests. Guidant concluded by stating that "[a]fter you have had an opportunity to analyze those materials, we should plan to meet again to discuss discovery issues." (*Id.* at 7). Three business days later, before Guidant had the opportunity to produce documents and without conducting the required "meet and confer," Relator filed its present Motion to Compel.

III. ARGUMENT

A. Relator's Motion to Compel is procedurally improper and premature

The Federal Rules of Civil Procedure require a movant in good faith to confer or attempt to confer with the party allegedly not responding to discovery in an effort to secure the discovery without court action. Fed. R. Civ. P. 37(a)(2)(A). In addition, the Local Rules of this Court require counsel for the parties to prepare a joint written statement of the matters at issue in the discovery "[p]rior to filing any discovery motion." Local Rule 37.01(a). The Local Rules also reiterate the requirement for a statement certifying that the movant has conferred with opposing counsel in a good faith effort to resolve by agreement the issues raised. Local Rule 37.01(b)(3). Finally, Judge Trauger's Practice and Procedure Manual requires that "[e]very effort should be made by the attorneys to resolve discovery disputes before bringing them to the Court's attention." (Excerpt of Manual attached as Exhibit 9) (emphasis added).

Relator's counsel failed to do any of these things. Although Relator's counsel belatedly filed a statement certifying that they conferred with Guidant's counsel in a good faith attempt to resolve the dispute, the facts are otherwise. (Docket No. 191). After receiving Guidant's May 25 letter, Relator's counsel made no effort to contact Guidant's counsel to

resolve the outstanding disputes (let alone to coordinate the drafting of a joint written statement). Indeed, Relator's counsel failed even to extend Guidant the courtesy of disclosing that they intended to file a motion to compel and for sanctions. Relator's counsel's failure to confer not only violates the Rules, but it is particularly disappointing given Guidant's counsel's specific invitation to "meet again to discuss discovery issues" after Relator had reviewed Guidant's initial document production. (Exhibit 8 at 7).

In addition to being procedurally improper, the Motion is premature. Guidant is in the midst of a rolling production. It has produced document retention policies, warranties, physician and patient marketing communications mentioning warranties, sales training presentations given to customers regarding warranties, and the documents it has gathered to date regarding Robert Fry's and Timothy McDonald's personnel files. (Letters from M. Desai to R. Fisher transmitting documents, attached collectively as Exhibit 10). Guidant has further assured Relator that it is in the process of gathering additional responsive documents and will be producing them shortly. (Exhibit 8). Guidant expected that the parties would further refine discovery after its production. (*Id.*) Relator, however, has rebuffed Guidant's attempt to engage in good-faith efforts to avoid motion practice. Tellingly, Relator recognizes that his Motion is premature and has informed the Court that he will withdraw issues "to the extent that the parties are able to resolve any" disputes. (Docket No. 190 at 4).

B. Relator's Motion to Compel creates disputes that do not exist

Curiously, Relator's Motion to Compel seeks to enlarge the number of discovery disputes between Relator and Guidant. Relator does this by ignoring Guidant's May 25 letter, which resolves several of Relator's complaints, and by seeking to create disputes where reasonable people would find none.

1. Two major issues in Relator's Motion to Compel have been resolved

First, Relator incorrectly claims that his Motion was necessitated because Guidant's May 25 letter "does not so much as discuss in detail the one thing [Guidant] had agreed to do at the face to face meeting – produce documentation of transactions at three hospitals over a three year period," and, therefore, "Relator believes that in the absence of this motion, there will be no production of documents directly relevant to his core allegations." (Docket No. 190 at 4) (emphasis added). Relator's statements are troubling because in its May 25 letter, Guidant confirmed its verbal agreement – and actually went a step further. Guidant stated that it:

> anticipates providing all records of Patients A-E, as well as records of replacement device implants performed [over a seven-year period] on or after January 1, 2000 at the three hospitals mentioned in the original and Second Amended Complaints in the near future.

(Exhibit 8 at 7).

Second, Guidant confirmed its agreement to produce documents containing confidential patient information after the entry of an appropriate Protective Order. Relator, however, demands that such documents be produced immediately pursuant to a September 13, 2006 Order, which permitted the limited disclosure of confidential information to Relator. (Docket No. 123). Relator, however, ignores the fact that after the entry of this Order, the United States intervened. As such, the United States has taken over the case and the United States justifiably informed Guidant that two additional and different protective orders were necessary. The September 13, 2006 Order did not contemplate the production of confidential information to the United States – the principal plaintiff in the case now – nor was the United States bound by

it. Simply put, the United States' intervention required the entry of additional protective orders before Guidant could produce confidential information.

Guidant and the United States have engaged in good-faith efforts to reach agreement on these additional orders. The parties have agreed to one order, dealing with the disclosure of confidential patient data, and are nearing an agreement on the other. Relator's hyperbolic contention that Guidant has "dragged out discussions" of the orders "with no end in sight" is simply incorrect. (Docket No. 190 at 7). Importantly, as Guidant advised Relator, Guidant's good-faith negotiations over the terms of these orders in no way affected Guidant's collection of responsive documents which has been ongoing.

2. Guidant believes that there is no reasonable dispute for the Court to resolve on several topics

(a) Manner of Production: Relator complains that there is a dispute regarding the manner of producing documents because Guidant has not objected to producing documents in a manner that permits Plaintiffs to locate and identify the information readily and to producing responsive documents in the format in which they are maintained. (Docket No. 190 at 5). In its seven-page, single-spaced response to Relator's April 13 letter, Guidant did not believe it was necessary to explain the obvious: that it would abide by Federal Rules of Civil Procedure 33-34, to which Relator apparently makes reference. The fact that Relator has not found fault with the manner in which Guidant has produced documents to date underscores that Relator seeks court intervention on a matter that is not, in fact, a matter of genuine dispute.

(b) Privilege Log: Relator acknowledges that Guidant has stated that it will provide a privilege log in conformity with Federal Rules of Civil Procedure 26(b)(5) should it withhold relevant documents on the basis of privilege. Guidant has also stated that although it cannot estimate precisely when the log will be produced, it will likely produce its log after the

majority of the responsive, non-privileged documents have been produced. Relator does not explain how this procedure is unreasonable for a case involving a large number of documents such as this one, or how this approach is at odds with the Rules.

(c) Definition of "Health Care Provider": Relator seeks a Court order requiring Guidant to produce documents notwithstanding Guidant's objections to Relator's definition of "Health Care Provider." In fact, there is nothing to compel, as Guidant has already assured Relator that it will produce documents notwithstanding this objection. Relator knows this, but attempts to create a dispute by contending that Guidant's well-meaning offer to revisit the definition of "Health Care Provider" after Gudiant produces documents if Relator has any concerns is somehow evidence of Guidant's nefarious intent to avoid doing what it has already agreed to do. Relator's interpretation of Guidant's good-faith efforts to cooperate is frivolous.

(d) "Reasonably Available": Relator complains about Guidant's statement that it will produce documents that are "reasonably available" and in conformity with the Rules. Tellingly, Relator does not ask for any specific relief from the Court on this point. Indeed, he cannot because his complaint is entirely unreasonable in light of Guidant's assurance that it will comply with the Rules which expressly reference the concept of reasonable availability. Moreover, the United States has taken the same position expressed by Guidant on this issue.

(e) Request No. 4: Relator requested "[d]ocumentation of any warranty credits extended to or paid to any person." Guidant responded by informing Relator that "Guidant issues credit . . . to the hospital in the name of the patient" and by agreeing to produce documentation of warranty credits. There is no dispute; Guidant will produce warranty credit information. Relator's Motion attempts to create a dispute by bootstrapping an argument that Guidant must also produce documentation of unreimbursed medical expenses paid to patients, if

any, despite the fact that Request No. 4 seeks only "documentation of warranty credits." In any event, by definition, unreimbursed medical expenses are not submitted to the government for payment, and as such, unreimbursed medical expenses could not constitute false claims because they could not be "claims."

(f) Request No. 7: Relator requested "Returned product forms and all similar documents relating to the return of explanted devices." Guidant objected that "all similar documents" was vague and confusing, but agreed to produce an exemplar copy of a returned-product form. In response, Relator refused to clarify its request: "There is nothing confusing or vague about this request." (Exhibit 6). In the absence of clarification, Guidant suggested that Relator review the documents it was producing and reconsider its request. Instead, Relator filed its Motion. Guidant has already agreed to produce an exemplar copy of a returned-product form. Moreover, Guidant will produce documentation regarding relevant devices, including reasonably-available, completed returned-product forms. It is unclear why Relator assumes that there is undefined "separate documentation" and Relator refuses to explain himself.

(g) Request No. 15: Relator requests all "brochures or other marketing materials concerning Guidant devices given to patients, physicians or health care providers . . . ." Guidant stated that it would produce "product brochures and other marketing materials made available to patients, physicians, and healthcare providers." Relator initially complained to Guidant that its use of "made available" was "disingenuous," but did not explain why. (Exhibit 6). Guidant explained that there was no difference intended in the use of these terms – only an effort to be precise about what Guidant understood of the documents. Guidant assured Relator that it would be producing the documents Relator sought. (Exhibit 8). Notwithstanding this assurance, Relator now complains that it was improper for Guidant to "unilaterally" change "given" to

"made available." (Docket No. 190 at 20). Given these facts, Relator should not have raised this "complaint" with the court.

C. Relator's Motion to Compel seeks documents that are not relevant

1. The "Relevant Time" period begins in 2001

Relator erroneously contends that Guidant must produce documents from September 11, 1993 to the present. The relevant statute of limitations, however, precludes liability for alleged violations of the FCA prior to 2001.[3]

The statute of limitations in the FCA provides:

> (b) A civil action under section 3730 may not be brought –
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> (1) more than 6 years after the date on which the violation of section 3729 is committed, or
>
> (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,
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> whichever occurs last.

31 U.S.C. § 3731(b). In his Motion, Relator contends that since he filed his sealed Complaint on September 11, 2003, he can obtain discovery as far back as September 11, 1993. Relator, however, has previously conceded that the ten-year period in § 3731(b)(2) is inapplicable to him. (*See* Docket No. 81 at 18). Recent legal authority also confirms that a private *qui tam* relator cannot avail himself or herself of the ten-year statute of limitations in § 3731(b)(2). That provision is limited to the government. *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 722-26 (10th Cir. 2006). Notwithstanding his conceded

[3] This section addresses Relator's Request Nos. 1, 5, 15 and Relator's discussion of the "Relevant Period" in section A.4 of his Motion.

inability to compel discovery dating back to September 11, 1993, Relator indignantly demands precisely that discovery from Guidant in this Motion, arguing that because the United States has intervened, he is entitled to the government's longer, ten-year statute of limitations.[4]

Relator's claim turns on whether he can avail himself of the tolling period in § 3731(b)(2) by virtue of the United States' intervention. The Second Circuit recently and decisively dealt with this issue. The court held that in order to toll the running of the statute of limitations, the United States' Complaint-in-Intervention must be filed within six years of the commission of the alleged violation or three years of the United States' knowledge of the alleged violation. *United States v. Baylor Univ. Medical Center*, 469 F.3d 263, 268 (2d Cir. 2006). In holding that the critical date for limitations purposes is the date of filing the Complaint-in-Intervention, the Second Circuit explicitly rejected the proposition that the date of the relator's original complaint under seal was controlling. *Id.* at 268-69 (citing various district court cases with which it disagreed).

The Second Circuit held that Federal Rule of Civil Procedure 15(c)(2) did not permit the government's Complaint-in-Intervention to relate back to the relator's *qui tam* complaint. Rather, the Second Circuit found that relation back under Rule 15(c)(2) requires notice, which is not provided to a defendant when a relator files his or her *qui tam* complaint:

> [The] secrecy required by § 3730(b) [which provides that a relator's *qui tam* complaint is filed *in camera* and remains under seal for at least sixty days until the government decides to intervene] is incompatible with Rule 15(c)(2), because (as is well-settled) the touchstone for relation back pursuant to Rule 15(c)(2) is notice, *i.e.*, whether the original pleading gave a party 'adequate notice of the conduct, transaction, or occurrence that forms the basis of the claim or defense.'

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[4] The Relator also contends that Guidant "admitted that a longer [ten-year] period would apply if the United States intervened." (Docket No. 190 at 8). Guidant made no such admission. Guidant merely explained that the tolling period in 37 U.S.C. § 3731(b)(2) is directed to the United States and is inapplicable to a private relator. (Docket No. 41 at 16-19).

Baylor, 469 F.3d at 270 (citations omitted) (emphasis added). The Second Circuit's reasoning is supported by the dual rationales underlying the statutes of limitations and Rule 15(c). The Supreme Court has stated that statutes of limitations "represent a pervasive legislative judgment that it is unjust to fail to put the adversary on notice to defend within a specified period of time and that the right to be free of stale claims in time comes to prevail over the right to prosecute them." *United States v. Kubrik*, 444 U.S. 111, 117 (1979) (emphasis added). Similarly, the Supreme Court has explained that the rationale behind Rule 15(c) "'is that a party who has been notified of litigation concerning a particular occurrence has been given all the notice that statutes of limitations were intended to provide.'" *Baldwin County Welcome Ctr. v. Brown*, 466 U.S. 147, 159 n.3 (1984) (emphasis added). As such, the filing of the complaint-in-intervention may not relate back to the relator's original sealed *qui tam* complaint. *Id.*; *see also United States ex rel. Wilkins v. North American Const. Corp.*, No. Civ. A. H-95-5614, 2001 WL 34109383, *13-14 (S.D. Tex. 2001) (holding that the United States' complaint-in-intervention regarding common law fraud claims was time-barred because a "complaint filed under seal [by a relator] does not provide notice to a defendant . . . [and it] does not ordinarily toll the running of a statute of limitations.") (attached as Exhibit 11).

Under 37 U.S.C. § 3731(b)(2), if the United States files its complaint-in-intervention within three years "after the date when facts material to the right of action [were] known or reasonably should have been known . . .," the United States may assert claims arising up to ten years prior to the date it gained knowledge of the facts. The Relator filed his Complaint on September 11, 2003. At that point, the United States knew or reasonably should have known the facts material to the right of action. *See Baylor*, 469 F.3d at 268 (dismissing the United States' claims, in part, because they were filed more than three years after the relator's

complaint). Accordingly, to avail itself of the benefits of § 3731(b)(2), it was incumbent on the United States to file its Complaint-in-Intervention on or before September 11, 2006. *Id.* While the United States intervened on November 2, 2006, it has yet to file a Complaint-in-Intervention. Here, the United States' intervention occurred more than three years after the date it obtained knowledge of the facts material to the action. Thus, its action cannot be tolled pursuant to § 3731(b)(2). The United States, therefore, is limited to the six-year statute of limitations in § 3731(b)(1). The applicable six-year limitations period, moreover, is measured from the filing of the government's Complaint-in-Intervention, an event which has not yet occurred. Assuming that the United States files its Complaint-in-Intervention today – June 18, 2007 – the relevant statute of limitations period will date back only to June 18, 2001, not September 11, 1993 as Relator contends.

Notwithstanding this limitation, in an effort to begin discovery, Guidant proposed producing documents dating back to January 1, 2000. This date was selected to permit cost reporting data from 2000, which might have impacted 2001 Medicare and Medicaid reimbursement claims if Relator's theory were true, to be discoverable. Guidant respectfully submits that this discovery period – which extends beyond the statute of limitations – should not be further enlarged and requests the Court to deny Relator's improper demand to expand discovery to September 11, 1993.

2. The allegations in the Second Amended Complaint are limited to replacement devices

The universe of devices implicated by Relator's allegations has been a moving target in Guidant's discussions with Relator's counsel. The allegations in Relator's Second

Amended Complaint implicate only information about replacement ICDs.[5] Replacement devices, however, constitute just a fraction of the devices about which Relator's overbroad discovery requests seek discovery. In his Motion, Relator begins by claiming that "Guidant disingenuously objects to Request number 2 . . . on the ground that only *replacement* of devices can trigger a credit . . . ." (Docket No. 190 at 11). Two pages later, however, Relator claims that during the May 8 meeting, he agreed with Guidant that his requests are limited to "replacement procedures." (*Id.* at 13).[6] It is possible that the parties may ultimately agree on this issue. Given Relator's rush to file a motion – on a Guidant position with which he now seems to agree – Guidant requests a clarifying Order from the Court.

In his Second Amended Complaint, Relator alleged that Guidant engaged in a fraudulent scheme to conceal the availability of warranty and Cardiassure credits from hospitals. (*See* Sec. Am. Compl. ¶ 14). Relator claims that because Guidant acted to keep hospital customers unaware of the warranty and Cardiassure credits, they did not take advantage of them to reduce the cost of replacement ICDs. (Sec. Am. Compl. ¶ 39). Relator alleges that, as a result, when Medicare or Medicaid covered a replacement implantation procedure involving a Guidant device, hospitals billed the full cost of the replacement ICD to the government, rather than a net cost reduced by warranty and Cardiassure credits from Guidant. (*Id.*) Accordingly, Relator claims that the government overpaid the hospitals. (*Id.*) By its terms, the Second Amended Complaint alleges a fraudulent scheme of concealing warranty and Cardiassure credits that, by definition, are only available when devices are replaced. Relator, however, has filed this

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[5] This section addresses Relator's Request Nos. 1, 2, 3, 7 and Relator's discussion of "Relevance Objections" in section A.7 of his Motion.

[6] Guidant, as it stated in its May 25 letter, did not understand this to be Relator's position. To the contrary, it believed that Relator's counsel rejected its offer to limit the scope of discovery to replacement devices. (Exhibit 8 at 4).

Motion to enforce discovery of all Guidant devices implanted and explanted in the entire United States, including territories such as Guam. There is no basis for permitting such overbroad and irrelevant discovery.

Rule 26(b)(1) provides that the parties "may obtain discovery regarding any matter . . . that is relevant to the claim or defense of any party . . . ." (Emphasis added). The 2000 Advisory Committee Notes explain that Rule 26(b)(1) was amended to its current form to "signal[] to the court that it has the authority to confine discovery to the claims and defenses asserted in the pleadings, and signals to the parties that they have no entitlement to discovery to develop new claims or defenses that are not already identified in the pleadings." (Emphasis added). *See also Dalka v. Sublett*, No. 01-2485V, 2002 WL 1482532, *1 (W.D. Tenn. April 30, 2002) (denying discovery because there were no allegations in the complaint relating to the issue on which discovery was sought) (attached as Exhibit 12). Information about non-replacement ICDs is not relevant to the false claims allegations asserted in the Relator's Second Amended Complaint because the credits at issue are available – if at all – only on replacement devices. Relator's Second Amended Complaint and his Motion concedes as much. (*See* Sec. Am. Compl. ¶¶ 52-69) (listing five examples in which warranty or Cardiassure credits were allegedly not issued for a replacement device); (*see* Docket No. 190 at 13) (stating that Relator only seeks information regarding replacement procedures).

As noted above, Guidant has proposed providing Relator and the United States with information concerning replacement devices from January 1, 2000 to the present for the three hospitals specified in Relator's original and Second Amended Complaints. Relator's objection to this approach appears to be prompted by the unfounded fear that Guidant will limit its production to information about the replacement device itself, and will not provide any

additional information about the predecessor device that is covered by the warranty or Cardiassure program. That is not the case and Relator's counsel have been repeatedly assured of that. The replacement device information Guidant intends to produce will include data about any predecessor device used by a patient receiving a Guidant replacement device at any of the three hospitals involved. Indeed, such information would be necessary to analyze the possible availability of any of the credits about which Relator makes allegations. Further, Guidant has an incentive to provide this contextual information as it supports Guidant's argument that Relator's claims are groundless.

Finally, Relator also chides Guidant for limiting discovery of upgrade and competitive replacement devices to the Cardiassure program. Guidant has already explained to Relator that device upgrade and competitive replacement programs are two parts of the Cardiassure program. Discussion about the Cardiassure program was not intended as a "limitation," but was intended to provide Relator with the name and structure of the program covering such credits. (Exhibit 8). In his Motion, Relator demands discovery on "alternatively titled upgrade and replacement programs that preceded the similar Cardiassure program." (Docket No. 190 at 15). However, the Cardiassure program began in 1998. For the reasons outlined in Section C.1, *supra*, the relevant statute of limitations bars discovery of "alternatively titled upgrade and replacement programs that preceded the similar Cardiassure program."

3. *Discovery of recalled devices is outside the scope of the Second Amended Complaint*

With regard to virtually every single request (Request Nos. 2, 3, 5, 10, 12, 14, 17, 18, 24, 27, and 28) Relator claims that Guidant has improperly excluded information about recalled devices from the scope of discovery. Relator is not entitled to discovery relating to recalled devices for two reasons. First, his Second Amended Complaint does not contain

allegations of how Guidant allegedly concealed "recall credits" from hospitals and physicians. Second, even if the scattered references to recalls in the Second Amended Complaint could be considered sufficient to support discovery, the minimal probative value of such information given Relator's case does not justify the expense to Guidant. Relator's theory of a secret scheme to avoid paying recall credits by concealing their availability to hospital administrators is entirely inconsistent with the highly visible reality of a FDA-approved nationwide recall.

1. Rule 26(b)(1) Does Not Permit Discovery of "Recalls"

Relator's desire to obtain discovery on recalled devices violates Rule 26(b)(1), which confines discovery to the claims and defenses asserted in the pleadings. *See discussion supra* at p. 16. The Relator's Second Amended Complaint is devoid of any allegations relating to any concealment (intentional, fraudulent, or otherwise) of credits related to recalled devices, thereby precluding discovery on recalled devices.

In the few instances in which the Second Amended Complaint speaks to the issue of recalls, the Relator alleges only that Guidant is required to "bear costs associated with" recalled devices, but has allegedly avoided paying such costs. (Sec. Am. Compl. ¶ 25). Relator, however, does not even attempt to explain the allegedly fraudulent scheme by which Guidant "avoided paying" costs associated with recalled devices. (*See id.* at ¶ 25, 55). Indeed, the Second Amended Complaint only references recalled Guidant devices in 5 out of 116 paragraphs. (*See id.* ¶ 25, 50, 54-56). Moreover, in none of those 5 paragraphs, does Relator allege whether or how Guidant supposedly concealed information about credits for the recalled device. (*See id.*). Even the Patient A "example" that Relator provides of the government supposedly having to pay full price for a device that replaced a recalled device does not state that Guidant concealed the cost of the replacement. Rather, Relator alleges only that Guidant

"avoided" the cost. (*Id.* at ¶ 56). Such an allegation, even if true, would not constitute an allegation of a "fraudulent scheme." Here, however, Guidant's investigation has shown that Relator's "example" is simply untrue. A full credit for the replacement device was issued by Guidant to the implanting hospital in the patient's name. (*See* Redacted Credit Memo, attached as Exhibit 13, and Declaration of Michael L. Koon, attached as Exhibit 14).

Relator's claim that Judge Trauger has already ruled that Relator had alleged a scheme to conceal recall credits is creative, at best. In finding that Relator met the specificity requirements of Rule 9(b), the Court ruled that the Second Amended Complaint sufficiently stated a cause of action based on an alleged fraudulent scheme to conceal warranty credits:

> Moreover, as this court previously held, an analysis of the record reveals that Mr. Fry has well met the Rule 9(b) pleading requirements for his FCA cause of action. Mr Fry, aside from alleging with particularity the overall scheme by which the defendant sought to preclude the hospitals from utilizing warranty credits, has in addition set forth five specific examples of upgrade procedures where hospitals were kept ignorant of those credits, and the cost was ultimately passed on to the federal government through Medicare.

(Docket No. 121 at 13-14) (emphasis added). The decision dealt specifically with warranty and upgrade credits, as does the Second Amended Complaint.

In deciding this motion to dismiss, Judge Trauger, of course, did not have the benefit of knowing that the one "example" Relator cited relating to credits in the context of device recalls was flatly untrue. It is hard to imagine that her decision would have been more expansive on the subject of recall allegations had a fuller record been before her. In any event, this Court needs to evaluate the appropriateness of Relator's discovery demands given the current status of the case, and not the sufficiency of the Second Amended Complaint. Because allegations relating to concealment of the cost (if any) of replacing a recalled device cannot be found in the Second Amended Complaint, discovery on this topic should be denied.

This is especially clear when the context of Relator's allegations are considered. Basic to Relator's false claim scheme is the notion of secrecy about the availability of replacement credits to hospitals. Relator alleges that hospitals are entirely dependent upon Guidant for warranty and Cardiassure credit information. As a result, the hospitals can be misled or kept ignorant of such information by Guidant. Even if these allegations were true in the warranty and Cardiassure contexts, they simply cannot be in the context of FDA-approved and announced recalls. Hospitals are virtually bombarded with information from sources outside Guidant in such cases. Widespread media coverage of such actions is only one way in which hospitals can and do learn of these developments outside of communications with the Company. Relator's allegations of a secret "scheme" to cheat hospitals and the government out of credits they supposedly had no idea they were owed cannot be sustained in a recall scenario. Relator's allegations of a "scheme" that requires universal ignorance by hospitals of recall credits are highly implausible. Given this implausibility, requiring Guidant to produce voluminous data about matters so clearly tangential to Relator's claim cannot be justified.

CONCLUSION

Relator's Motion to Compel is both premature and unfounded. Guidant has repeatedly sought to advance discovery in this case despite being the only party with no burden of proof. Many of Relator's complaints are makeweight, at best. Where disputes actually do exist, Guidant is entitled to relief. In light of both Relator's disregard for the Rules and Guidant's good-faith efforts to advance discovery, Relator's request for sanctions is entirely inappropriate. Guidant respectfully requests that the Court:

1. Deny Relator's Motion to Compel Responses to His First Request for Production of Documents to Defendant Guidant Corporation and for Sanctions;

2. Limit the period of discovery in this case to January 1, 2000 to the present;

3. Limit initial discovery to documents surrounding Patients A-E in the Second Amended Complaint and records concerning replacement devices implanted at the three hospitals identified in the Second Amended Complaint;

4. Bar Relator and the government from discovery of information about recalled devices absent a showing of good cause and a mechanism for cost sharing in making any such production;

5. Grant any such other relief as the Court deems just and proper.

Dated: June 18, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

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